5980. (F.D.C. No. 41714. S. Nos. 43-480 M, 84-124/5 M.)

INDICTMENT RETURNED: 1-14-59, E. Dist. Mo., against Isador Kammer, t/a Belt Avenue Pharmacy, St. Louis, Mo.

CHARGE: Between 8-8-57 and 10-25-57, secobarbital sodium capsules were dispensed once without a prescription, and dextro-amphetamine sulfate tablets were dispensed twice upon requests for a prescription refill without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 2-4-60. \$600 fine.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5941 TO 5980 PRODUCTS

ricoboots			
N.J. No. 1	N.J. No.		
Achromycin capsules ¹ 5967	Methamphetamine hydrochloride		
-SF capsules ¹ 5967	tablets * 5970		
AM Plus capsules 5973	Meticorten tablets 5961		
Amphetamine, dextro-, sulfate	Miltown tablets 5973		
capsules 5950	Nembutal capsules 5969,		
sulfate tablets 5951-5953, 5980	5971, 5975, ¹ 5977		
sulfate capsules 5943	Penicillin tablets 5963, 5964		
tablets 12 5941-5950	Pentids tablets 5955		
Amsustain tablets ¹ 5977	Pentobarbital sodium capsules 5951,		
Aristocort tablets 5965	5959, 5963, 5974		
Benzedrine Sulfate tablets * 5970,	Pen-Vee tablets 5969		
5976, 5978	Phenobarbital tablets 5964		
Butisol Sodium Elixir 5974	Piptelate tablets 5972		
Compocillin-V tablets 5966	Rauprote tablets 5972		
Dexamyl Spansule capsules 5954	Secobarbital sodium and amo-		
Dexedrine Spansule capsules 5973-	barbital sodium, capsules		
5975, ¹ 5977	containing a mixture of 5976,		
5975, * 5977 Sulfate tablets * 5954	5979		
5960, 5965, 5979	Secobarbital sodium capsules 5951,		
Dextro-amphetamine sulfate cap-	5955, 5960, 5980		
sules 5950	Seconal Sodium capsules 5961,		
tablets 5951-5953, 5980	5962, 5969, ¹ 5977		
Elixir, Butisol Sodium 5974	Synatan tablets 5962		
Gardophen5972	Thriocaine Lotion 5972		
Ergoapiol with savin capsules 5953	Thyroid tablets 5961, 5964		
Gantrisin tablets 5958, 5979	Triophen tablets 5972		
Gardophen elixir 5972	Tuinal capsules 5958, 15967,		
Lotusate tablets 5966	5968, 5975, ¹ 5977		
Medrol tablets 5964	V-Cillin K tablets 5971		
Meprobamate tablets 5951, 5961			
SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS			

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

N.J. No.	N	.J. No.
Adams, J. B.:	Allen, H. H.:	
thyroid tablets, Medrol tablets,	Pen-Vee tablets, Seconal So-	
penicillin tablets, and phe-	dium capsules, and Nembu-	
nobarbital tablets 5964	tal capsules	5969

¹ (5944, 5945, 5956, 5957, 5967, 5977) Prosecution contested.

² (5947) Prosecution contested. Contains opinion of the court.

^{3 (5970)} Violation of parole.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

usuant to section 705 of the Food, Drug, and Cosmetic Act]

5981-6000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default or by consent and (2) a criminal proceeding terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal proceedings are against the firms or individuals charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, Commissioner of Food and Drugs. Washington, D.C., September 7, 1960.

CONTENTS*

	Page		Page
Drugs actionable because of poten-	i.	Drugs actionable because of devia-	
tial danger when used accord-		tion from official or own stand-	
ing to directions	272	ards	282
Drug for human use	272	Drugs and devices actionable be-	
Drug for veterinary use	273	cause of false and misleading	
New drugs shipped without effec-		claims	283
tive application	273	Drugs for human use	283
Drug for human use	273	Drug for veterinary use	288
Drug for veterinary use	280	Index	289
Drugs actionable because of failure			
to bear adequate directions or			
warning statements	281	·	

^{*}For drugs in violation of prescription labeling requirements, see No. 5981; for omission of, or unsatisfactory, ingredient statements, see Nos. 5982, 5988.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 5981-6000

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(e) (2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DRUG FOR HUMAN USE

5981. Alcorem. (F.D.C. No. 41476. S. Nos. 13-268/9 P.)

QUANTITY: 260 btls. of fluid extract of ipecac root and 264 kits, each containing 1 btl. of fluid extract of ipecac root and 1 btl. of vitamin capsules at Chicago, Ill., in possession of Midwest Health Aids.

SHIPPED: (Fluid extract of ipecac root), 9-11-57 and 2-12-58, from New York, N.Y., and (vitamin capsules), from Chicago, Ill., on an unknown date.

Label in Part: (Kit) "Alcorem Kit * * * Contains bottle of Alcorem with dispenser, 21 Pinkies for Vitamin Deficiency, Weight Chart and Complete Instructions for home use," (btl.) "½ Ounce ALCOREM Emetic Brand of Fluid Extract of Ipecac – Alcohol 30%" and "21 Capsules Special PINKIES Capsules Natural Fortified Vitamin B Complex * * * Each Capsule Contains: Vitamin B-1 1,000 U.S.P. Units Vitamin B-2 3,000 Micrograms Vitamin B-6 125 Micrograms Calcium Pantothenate 3,000 Micrograms Niacin Amide 10,000 Micrograms."

Accompanying Labeling: Circulars entitled "Instructions For the Use of Alcorem for the Relief of Drunkenness," "Alcorem Weight Chart for Men and Women," "Housewife Praises Pinkies," "Important Read Carefully," "Special Quick Action Order Blank," and "Live Longer."

RESULTS OF INVESTIGATION: The fluid extract and the capsules had been repackaged into kits by the dealer from bulk stock which had been shipped as described above. The circulars were printed locally on order of the dealer.